



DEPARTMENT OF HEALTH AND HUMAN SERVICES

91619d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 8, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-75

William W. Himmelspach, Owner
22195 S.W. 78th
Tualatin, Oregon 97062

WARNING LETTER

Dear Mr. Himmelspach:

An investigation at your animal feed manufacturing operation located at 22195 S.W. 78th Tualatin, Oregon 97062, conducted by a Food and Drug Administration investigator on July 12, 2001, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed. The regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured at this facility to be adulterated within the meaning of Section 402(a)(2)(C), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigation found a failure to separate the receipt, processing, and storage of the product containing prohibited material from non-prohibited material; failure to establish a written system, including clean-out and flushing procedures, to avoid commingling and cross-contamination of common equipment; and failure to maintain records sufficient to track the materials throughout the receipt, processing, and distribution of your products.

In addition, our investigation found a failure to label your products with the required cautionary statement "**Do Not Feed to Cattle or Other Ruminants.**" Your pig feeds, containing prohibited materials, were not labeled with the cautionary statement, and you reuse poly-tote bags for ruminant feed and pig feed, where the bags could become contaminated with prohibited material. The FDA suggests the statement be distinguished by different type size or color or other means of highlighting the statement so that it is easily noticed by a purchaser.

The above is not intended to be an all-inclusive list of deviations from the regulations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with

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your overall operation and the products you manufacture and distribute are in compliance with the law. We have enclosed a copy of the FDA's Small Entity Compliance Guide to assist you with complying with the regulation.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Bruce Williamson, Compliance Officer. If you have any questions please contact Mr. Williamson at (425) 483-4976.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosure:
Form FDA 483
Small Entity Compliance Guide